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K011875

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SUMMARY OF SAFETY AND EFFECTIVENESS

A. SPONSOR IDENTIFICATION

NewDeal SA
Parc d'Activitiés Garigliano
Rue de la Convention
38 200 VIENNE
FRANCE
Tél. : (33) 4 74 78 15 15
Fax : (33) 4 74 78 15 16

B. ESTABLISHMENT REGISTRATION NUMBER: 9615741

C. OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph. D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac , MD 20854
estrin@yourFDAconsultant.com
Tel. : (301) 279-2899
Fax : (301) 294-0126

D. DATE OF PREPARATION OF THIS SUMMARY: June 14, 2001

E. PROPRIETARY (TRADE) NAME: **TAC'pin®**

F. COMMON NAME: Bone fixation wire, self tapping threaded wire

G. CLASSIFICATION NAME AND REFERENCE

Smooth or threaded metallic bone fixation fastener (21 CFR, Section 888.3040)

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H. PROPOSED REGULATORY CLASS: Class II

I. DEVICE PRODUCT CODE: 87JDW

J. PANEL CODE: 87 OR

K. DESCRIPTION OF DEVICE: The **TAC'pin®** is a self tapping threaded wire. Its proximal part is fixed on a standard surgical power tool equipment and once the threaded wire is introduced and positioned as required, the surgeon cuts the protruding part at the bone surface. The lengths of threads available are the following : 15 – 20 – 25 mm.. This pin is designed with a variable pitch, for a true and adapted compression.

L. INTENDED USE: The **TAC'pin®** is intended to be implanted for fixation of bone fractures or for bone reconstructions.

M. INDICATIONS FOR USE: The "new" **TAC'pin®** is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

Fixation of small bone fragments, in long bones or small bones fractures.

- Arthrodesis in hand or foot surgery
- Mono or Bi-cortical osteotomies in the foot or hand
- Distal or proximal metatarsal or metacarpal osteotomies
- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)

N. PREDICATE DEVICE The **"new" TAC'pin®** is technically equivalent to the **TAC'pin®** currently approved (K993910). The **"new" TAC'pin®** is substantially equivalent to the Threaded fixation pin manufactured by Sgarlato laboratories (K982931), and the Kirschner wires and Steinmann pins manufactured by Syntec-Taichung Medical Instruments (K983121).

O. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The **"new" TAC'pin®** is technically equivalent to the device currently approved. They have the same intended use, the same material, and the design of the active part (threaded part) has not changed. The following design change should however be noted : The diameter of the proximal (non threaded) part of the pin has been decreased from 1.7mm to 1.6mm, for a better adaptation to power drills (wire drivers) commonly used by the surgeons. This has not changed anything to the "active" part of the pin, as this proximal part of diameter 1.6mm is cut by the surgeon once the pin is in place. It does not remain in the patient.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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New Deal SA
c/o Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K011875
Trade/Device Name: TAC'pin®
Regulation Number: 888.3040
Regulatory Class: II
Product Code: JDW
Dated: June 14, 2001
Received: June 15, 2001

Dear Dr. Estrin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Walker, M.D.

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CONFIDENTIAL

510(k) Number (if known): K011875

Device Name: **TAC' pin** ®

Indications for Use:

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- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
OR Over-the-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011875